REMARKS

Claims 1-8 are pending in the present application, wherein claim 8 is new.

Claim 8 has been added as another embodiment of the present invention. Support for new claim 8 can be found in the specification at least at page 4, lines 24-25. No new matter has been added.

Pending claims 1-8 considered together with the following remarks are believed sufficient to place the application into condition for allowance. Accordingly, an early and favorable action on the merits is earnestly solicited at present.

Issue Under Provisional Ovbiousness-type Double Patenting

Claims 1-7 stand provisionally rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending US Application 11/060,775.

In response to this provisional rejection, Applicants request that the Examiner hold this provisional rejection in abeyance until allowable subject matter is achieved in one application, and then make the rejection nonprovisional in the other application. This is the procedure recited in the M.P.E.P. § 804.

Issues Under 35 U.S.C. § 103(a))

Claims 1, 2, 5 and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Terashima *et al.* ('278) (US 4,839,278)**.

Claims 3 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Terashima *et al.* ('278) (US 4,839,278)** in view of **Hildenbrand *et al.* ('639) (US 4,824,639)**.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over **Terashima et al. ('278) (US 4,839,278)** in view of **Tanaka et al. ('457) (US 4,990,457)**.

Reconsideration and withdrawal of the above rejections are respectfully requested based on the following considerations.

The Present Invention

The claimed invention is drawn to a multilayer analysis element for liquid sample analysis wherein at least one functional layer and at least one porous liquid sample spreading layer of non-fibrous porous film are integrally laminated in this order on one side of a water-impermeable planar support, and the non-fibrous porous film has a bending rupture strength of 20 gram-weight or more and a tensile percentage of 2% or less when the film is stretched with a tensile force of 50 gram-weight (see, e.g., claim 1).

Distinctions Over the Cited Modification of Terashima et al. '278 and Combinations Thereof

Terashima *et al.* ('278) (US 4,839,278)

Terashima *et al.* ('278) disclose a multilayer analysis element for liquid sample analysis. However, Terashima *et al.* ('278) do not disclose a porous liquid sample spreading layer of "non-fibrous" porous film which is an essential feature of the present invention. Terashima *et al.* ('278) teach fibrous film, but do not teach "non-fibrous" porous film. The materials listed in Terashima *et al.* ('278) mostly relate to fibrous films. Applicants also note paragraph 7 of the Office Action, wherein the disclosure of Terashima *et al.* ('278) is discussed but the instantly claimed non-fibrous porous film is not mentioned. In other words, Terashima *et al.* ('278) is

deficient more so than what is discussed in the Office Action (e.g., values for bending rupture strength, etc.)

Applicants also agree with the Examiner in that Terashima *et al.* ('278) does not teach the claimed values for bending rupture strength, tensile percentage, or tensile force. However, such claimed features are not a matter of "optimization". Applicants note that no evidence has been set forth to account for these claimed features (see, e.g., paragraph 7 of the Office Action).

Furthermore, Terashima *et al.* ('278) does not teach the advantage or preference for these defined claimed values. Accordingly, Terashima *et al.* ('278) does not provide the proper rationale, teaching, suggestion, motivation, or guidance that would yield predictable results in regards to the claimed bending rupture strength, tensile percentage, or tensile force (see discussion of case law below, including the recent *KSR Int'l* decision).

In the present invention, claims 1-8 recite that the non-fibrous porous film has a bending rupture strength of 20 gram-weight or more, and a tensile percentage of 2 percent or less when the film is stretched with a tensile force of 50 gram-weight. Applicants contend that by adopting such features, the multilayer analysis element of the invention achieves advantageous effects such as improved sensitivity (see Tables 3, 5, and 7), (*sensitivity comparison*), and improved measurement accuracy (see Tables 4, 6, and 8), (*accuracy comparison*), improved nonuniformities in reflected light quantity (see Table 9) and high accuracy when a photometric area is reduced (see Table 10). Despite the assertion of optimization, Terashima *et al.* ('278) gives no indication that such advantages could be achieved.

In regards to claim 8, which is limited to polyether sulfone or a mixture of polyether sulfone and polysulfone into the **non-fibrous** porous film, this limitation is described in the

specification on page 4 and comparison evaluation results are shown in Table 1 (*bending comparison*), Table 2 (*stretching comparison*), Tables 3, 5, and 7 (*sensitivity comparison*), Tables 4, 6, and 8 (*accuracy comparison*) of the specification. The data in the Tables confirm the advantages of a **non-fibrous** porous film comprised of a polyether sulfone or a polysulfone. Regarding such advantages achieved by the present invention, Terashima *et al.* ('278) again does not provide proper the proper rationale, teaching, suggestion, motivation, or guidance in yielding predictable results from the use of a **non-fibrous** porous film, and in particular, a multi-layer analysis element comprising a polyether sulfone, a polysulfone, or a mixture of polyether sulfone and polysulfone.

Hildenbrand *et al.* ('639) (US 4,824,639)

Regarding the combination of Terashima *et al.* ('278) and Hildenbrand *et al.* ('639), Hildenbrand *et al.* ('639) does teach a multilayer test strip comprised of a microporous polymer layer with an asymmetric pore structure. However, the Examiner admits that neither Terashima *et al.* ('278) nor Hildenbrand *et al.* ('639) teach or suggest an asymmetry ratio of 2 or more, nor do they teach a asymmetry ratio of less than 2. And further regarding the lack of disclosure in the primary reference as discussed above, neither Terashima *et al.* ('278) nor Hildenbrand *et al.* provide the proper rationale, teaching, suggestion, motivation, or guidance yielding predictable results for the use of a **non-fibrous** porous film. Therefore, the additional cited art of Hildenbrand *et al.* ('639) is incapable of curing the above noted deficiencies of Terashima *et al.* ('278), and thus are incapable of rendering the instant invention as claimed obvious.

Tanaka et al. ('457) (US 4,990,457)

Regarding the combination of Terashima *et al.* ('278) and Tanaka et al. ('457), Tanaka *et al.* ('457) merely disclose that polysulfones may be in a porous layer. However, even though this is known in the prior art, there is no suggestion of the advantages of a multilayer test strip comprised of **non-fibrous** porous film. Therefore, the additional cited art of Tanaka et al. ('457) is incapable of curing the above noted deficiencies of Terashima *et al.* ('278), and thus are incapable of rendering the instant invention as claimed obvious.

Legal Standard for Determining Prima Facie Obviousness

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper.

The rationale should be made explicit, *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), and the Examiner must interpret the reference as a whole and cannot pick and choose only those selective portions of the reference which support the Examiner's position. *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.").

As the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP § 2143.03.

MPEP § 2143.03 recites examples of Basic Requirements of a *Prima Facie* Case of Obviousness and seven exemplary rationales.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

However, Applicants fully address these rationales below. According to Applicants analysis below, the Examiner has not met the basic requirements of a *prima facie* case of obviousness. More specifically, Applicants contend that:

(A) Combining prior art elements according to known methods cited do not yield predictable results for a multilayer analysis element for liquid sample analysis wherein at least one functional layer and at least one porous liquid sample spreading layer of non-fibrous porous film;

(B) Simple substitution of one known a multilayer analysis element for liquid sample analysis, does not yield predictable results in regards to a multilayer analysis element for liquid sample analysis comprising a porous liquid sample spreading layer of "non-fibrous" porous film;

(C) There is no known technique to improve a multilayer analysis element which would one skilled in the art to use a one porous liquid sample spreading layer of non-

fibrous porous film, and in particular, incorporate a polyether sulfone or a mixture of polyether sulfone and polysulfone into the **non-fibrous** porous film;

(D) Applying known techniques as taught by Hildenbrand *et al.* ('639) and Tanaka *et al.* ('457) do not yield predictable results for said a multilayer analysis element for liquid sample analysis comprising a porous liquid sample spreading layer of "non-fibrous" porous film as claimed;

(E) The Examiner cannot support the conclusion of "obviousness" on the basis "Obvious to try" – there are no predictable methods or models cited by the Examiner that establish a reasonable expectation of success for said methods considering that it was not known how **non-fibrous** porous film would interact in a multilayer analysis element;

(F) There is no reason or rationale cited by the Examiner that may prompt variations from the disclosure of Hildenbrand *et al.* ('639) and Tanaka *et al.* ('457) that would result in the claimed multilayer analysis element;

(G) There is no proper teaching, suggestion, motivation, and/or reasonable expectation of success that would yield predictable results in the prior art as cited by the Examiner that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed multilayer analysis element for liquid sample analysis wherein at least one functional layer and at least one porous liquid sample spreading layer of non-fibrous porous film.

Overall, as discussed above, Terashima *et al.* ('278) fail to disclose the instantly claimed non-fibrous porous film, and this feature has not properly accounted for in the Office Action. The cited secondary references fail to cure the deficiencies of the primary reference. Accordingly, the present invention is *not* rendered obvious in view of the teachings and disclosures of the cited modification of **Terashima *et al.* ('278)**, and/or the further combination of **Terashima *et al.* ('278)** with **Hildenbrand *et al.*** or **Tanaka et al. ('457)**. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eggerton A. Campbell, Reg. No. 51,307, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

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